

# EXHIBIT A

**UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY	)	
AVERAGE WHOLESALE PRICE	)	MDL NO. 1456
LITIGATION	)	Civ. Action No. 01-12257-PBS
	)	
THIS DOCUMENT RELATES TO:	)	Judge Patti B. Saris
	)	
<i>The City of New York v. Abbott Labs., Inc., et al.,</i>	)	
S.D.N.Y. Case No. 04-CV-06054	)	
	)	<b>ORAL ARGUMENT</b>
<i>County of Albany v. Abbott Labs., Inc., et al.,</i>	)	<b>REQUESTED</b>
N.D.N.Y. Case No. 05-CV-0425	)	
	)	
<i>County of Allegany v. Abbott Labs., Inc., et al.,</i>	)	
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**DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF THEIR JOINT  
MOTION TO EXCLUDE THE PROFFERED EXPERT REPORT AND  
TESTIMONY OF HARRIS DEVOR, C.P.A.**

<i>County of Cortland v. Abbott Labs., Inc., et al.,</i>	)
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<i>County of Greene v. Abbott Labs., Inc., et al.,</i>	)
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## INTRODUCTION

Stripped of its rhetoric, Plaintiffs' Opposition ("Opp.") does not, and cannot, dispute two dispositive facts that require the exclusion of Mr. Harris Devor's opinions, calculations and testimony.

First, Plaintiffs admit that Mr. Devor has not been offered to establish, let alone support, any plausible theory of "FUL-fraud" causation. *See* Opp. at 12. Because causation is the *very issue* on which expert opinions have been ordered by this Court with respect to FUL drugs, it necessarily follows that Mr. Devor's opinions and calculations are irrelevant and must be excluded.

Second, Plaintiffs do not dispute and apparently concede that Mr. Devor's analysis frequently results in wholly nonsensical "estimated" WACs and AWP. In fact, Plaintiffs do not dispute that where Mr. Devor calculated an "estimated" WAC and/or AWP:

- nearly 90% of his "estimated" AWP were *less than* the reported AMPs for at least one quarter;
- over a third of Mr. Devor's "estimated" AWP were *less than* the AMPs for the same NDC;
- 60% of his "estimated" WACs were *greater* than his "estimated" AWP;
- 90% of his "estimated" WACs were *greater* than his "estimated" AWP for at least one quarter;

- over 10% of his “estimated” AWP or WACs were *negative*; and,
- in over 40% of the NDCs for which either an “estimated” AWP or WAC was computed, at least one of the two was negative for at least one quarter.

Not only do Plaintiffs apparently concede that Mr. Devor’s calculations yield such nonsensical results, Plaintiffs openly admit that Mr. Devor’s “estimated” WACs and AWP’s violate expected “real-world relationships,” *see id.* at 3—relationships Mr. Devor himself has acknowledged and embraced as “normal.” *See* Dec. Devor Dep. at 161:11-13, 167:2-9 (attached as Exhibit 4 to Defendants’ Motion). While Plaintiffs attempt to deflect this criticism, suggesting Defendants displayed “unmitigated nerve” to highlight the failings of Mr. Devor’s methods, Plaintiffs cannot meaningfully dispute the staggering inconsistencies in Mr. Devor’s purported analyses and methodology. Nor can they dispute that even when presented with these inconsistencies, Mr. Devor has chosen not to alter (or explain) his methodology. The reason, of course, is that there is no explanation for how his methodology could produce such results and still be reliable, let alone relevant to the central issue presented—*i.e.*, causation.

In short, these concessions compel the conclusion that Mr. Devor’s opinions and testimony must be excluded in their entirety. As discussed further below, the other arguments raised by Plaintiffs rest on misunderstandings or misstatements of law, inapposite factual differences, or classic “red herrings” which do not and cannot alter the conclusion that Mr. Devor’s opinions and testimony fail to satisfy the minimum standards for admissibility under Fed. R. Evid. 702 and *Daubert*.

### ARGUMENT

Plaintiffs forward a truly novel understanding of this Court’s gatekeeping role over expert testimony. According to Plaintiffs, the Supreme Court’s *Daubert* decision “does not stand for the proposition that courts are to replace juries in respect of findings about the relative weight, credibility, or conclusions of competing experts.” *Opp.* at 10. And because in their view “Defendants do not attack Mr. Devor’s methods of calculation

or estimations,” but instead “say that the conclusions [Mr. Devor] draws do not support the claims made,” Plaintiffs posit that such a challenge should be made “to a jury, not the court on a *Daubert* motion.” *Id.* at 11. This argument is irrelevant, legally incorrect and factually misplaced.

*First*, as a legal matter, Defendants obviously agree that, in the context of a jury trial, once evidence is deemed admissible by the Court, the ultimate weight given that evidence is a question for the jury. But this truism misses the point: the jury’s role as factfinder is secondary to and dependent upon the court’s responsibility to decide the threshold question of whether evidence (expert or otherwise) is admissible. Fed. R. Evid. 104(a). Indeed, that is precisely the purpose of the gatekeeping function, where district courts are presented with challenges to *the admissibility* of a purported expert’s opinions and testimony on a *Daubert* motion. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993); Fed. R. Evid. 702; *Kumho Tire Co. Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999).

The district court’s “role is to keep unreliable and irrelevant information from the jury because of its inability to assist in factual determinations, its potential to create confusion, and its lack of probative value.” *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1311-12 (11th Cir. 1999); *Hochen v. Bobst Group, Inc.*, 290 F.3d 446, 452 (1st Cir. 2002) (Rule 702 “assigns to the trial judge the responsibility for ensuring that an expert’s testimony as to scientific, technical or other specialized knowledge both rests on a reliable foundation and is relevant to the task at hand.”) (citations omitted). Defendants’ Motion -- like all properly-framed *Daubert* motions -- focuses on the inadmissibility of the irrelevant and unreliable calculations performed by Mr. Devor. This is the very heartland of a Rule 702/*Daubert* motion, not a question of weight reserved for the jury.

In addition, as the very authority cited by the Plaintiffs makes clear, Plaintiffs are wholly mistaken in their argument that the conclusions that Mr. Devor draws from his purported methodology go solely to weight and not to admissibility:

‘[C]onclusions and methodology are not entirely distinct from one another. . . . [N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.’ Thus, when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony.

*Amorgianos v. Ntl R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)) (citing *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 153 (3d Cir. 1999)).

Moreover, it is well-settled that where, as here, an expert such as Mr. Devor cannot present any opinions that in the end will “assist the trier of fact to understand the evidence or to determine a fact in issue,” *Daubert*, 509 U.S. at 591 (citation and quotations omitted), those opinions are not relevant, because they do not “logically advance [] a material aspect of the proposing party’s case.” *Allison*, 184 F.3d at 1312. This is particularly so where, as here, the “only connection between the [expert’s] conclusion[s] and the existing data [was] the expert’s own assertions.” *McDowell v. Brown*, 392 F.3d 1283, 1300 (11th Cir. 2004) (citation omitted).

*Second*, as a factual matter, Plaintiffs are simply incorrect that Defendants “do not attack Mr. Devor’s methods of calculation or estimations,” but rather merely “the conclusions he draws.” Opp. at 11. Contrary to Plaintiffs’ accounting, Defendants have catalogued in exhaustive detail the errors and discrepancies in Mr. Devor’s calculations, and how those errors (coupled with the failure to account for or explain them) rendered them inherently unreliable. See, e.g., Defendants’ Memorandum in Support of Motion to Exclude at 7-12, 17-19. Nor are Plaintiffs correct in stating that “defendants’ motion



to exclude does not and cannot attack the purely mathematical exercise” utilized by Mr. Devor is calculating “estimated” FULs. Opp. at 15. The error in utilizing that aptly-named “purely mathematical exercise” is one of the animating principles behind Defendants’ relevancy and reliability arguments; *viz.*, that Mr. Devor’s purported methodology is completely untethered from reality in that his methodology bears no relationship to that actually employed by CMS. For example, as explained in Defendants’ Motion, Mr. Devor calculates up to three different “estimated” FULs for each NDC, even though CMS calculates one FUL for all NDCs in the same GCN, and he unfailingly multiplies his “estimated” WACs and AWP by 150% even though, with respect to the nine GCNs at issue here, CMS only used that formula 20% of the time.

In short, Plaintiffs both misapprehend and misapply the legal principles underlying a proper *Daubert* challenge, and the specific challenges raised by Defendants. These arguments cannot and do not change the fact that Mr. Devor’s testimony and calculations are both irrelevant and unreliable.<sup>1</sup>

Plaintiffs next contend that this Court does not need Mr. Devor “to opine as to defendants’ legal obligations to report true prices.” Opp. at 5. But Defendants have never argued that the Court did need such testimony. What Defendants have consistently (and correctly) argued is that Mr. Devor (or some other expert for Plaintiffs) is required to demonstrate that *something that Defendants did* caused CMS to set “inflated” FULs. *See In re Pharm. Indus. Avg. Wholesale Price Litig.*, 498 F.

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<sup>1</sup> Plaintiffs also argue that Mr. Devor should not be excluded because Defendants have not offered “counter-expert conclusions that any of their reported prices were correct,” Opp. at 2, or any WAC List Price Test results in connection with the drugs at issue, *id.*, or any “alternatives” to Mr. Devor’s “estimated” FULs, *id.* at 13. This is simply a red-herring. There is no requirement that any of these showings be made in order for this Court to adjudge the relevance or reliability of Mr. Devor’s opinions and methodology. Moreover, the so-called “WAC List Price Test” and “AWP spread test,” were derived in the context of expectations regarding brand-name drugs. As such, they have no relevancy whatsoever to FUL related issues and the generic drugs at issue here.

Supp. 2d 402, 405 (D. Mass. 2007) (ordering that Plaintiffs “shall specifically make allegations” “that defendants submitted false or inflated *published* prices which, if truthful, would likely have affected the FUL”) (emphasis in original).

Plaintiffs have not done so. Nor, contrary to Plaintiffs’ suggestion, would such testimony be “inadmissible.” *See* Fed. R. Evid. 704 (“[T]estimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.”).<sup>2</sup> The true irony here is that what Plaintiffs now claim Mr. Devor has been offered to opine upon -- that Defendants’ WACs are not “true” but Mr. Devor’s are -- actually is a question of law and therefore inadmissible. *See In re Rezulin Prods. Litig.*, 309 F. Supp. 2d 531, 541 (S.D.N.Y. 2004) (explaining that while “an expert may give an opinion to help the jury decide an issue in the case, *he or she may not tell the jury what result to reach*”) (emphasis supplied). In any event, and contrary to Plaintiffs’ new characterization of Mr. Devor’s “estimated WACs” as so-called “true WACs,” *see* Opp. at 4, Mr. Devor himself testified that he did not believe that Defendants (let alone CMS) should have used his methodology, *see, e.g.*, Dec. Devor Dep. at 55:5-8, 12-16, and he offers no opinion that Defendants’ published prices were “false,” *i.e.*, not “true WACs.” This latter point is telling, given the fact that Plaintiffs in their Opposition attempt to redefine Mr. Devor’s opinion as focusing on

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<sup>2</sup> Plaintiffs also argue that only CMS can answer this question, and point to a declaration that supposedly says that Mr. Devor’s “estimated” FULs would have been utilized instead of the FULs CMS actually used. Opp. at 4. For the reasons set forth in Defendants’ reply brief on summary judgment, though, that argument is unavailing, because that declaration actually confirms just how discretionary and context-based choosing FULs was and is. *See* 6/15/09 Defendants Joint Reply In Further Support of Their Motion For Summary Judgment and In Opposition to Plaintiffs’ Motion For Partial Summary Judgment (Dkt. No. 6218) at 6-13. In fact, contrary to Plaintiffs’ repeated (mis)characterization of this declaration, it does not and cannot alter the undisputed record establishing that CMS exercised its discretion and repeatedly chose to disregard lower published prices in setting the FUL in order to achieve important policy objectives. Indeed, because CMS repeatedly disregarded lower published prices when setting the FUL, Plaintiffs cannot plausibly demonstrate that CMS would have opted to use Mr. Devor’s even lower (in fact, very often negative) so-called “alternative true WACs” in setting any FUL.

what “defendants’ true WACs” are. Opp. at 4. At bottom, Plaintiffs’ attempt to re-cast Mr. Devor’s opinions as somehow relevant to their (legally incorrect) reading of New York Social Services Law § 145-b is unavailing.

Plaintiffs next argue that “[w]hether Mr. Devor’s expertise in another matter has been challenged has nothing to do with the matter at-hand” because “[w]hether or not a particular expert’s testimony is admissible is considered on a case-by-case basis.” Opp. at 8-9. Plaintiffs fail to recognize that this principle cuts both ways. Whether or not Mr. Devor has been permitted to offer opinions in other AWP cases with respect to “damages” calculations, or in securities fraud cases, is irrelevant to whether or not the opinions he would like to offer in *this case* are relevant and reliable as required under *Daubert* and Rule 702.

Plaintiffs efforts to distinguish two other cases in which Mr. Devor has been disqualified as an expert similarly miss the point. Plaintiffs first argue that this case is different than *In re Acceptance Ins. Cos. Inc., Sec. Litig.*, 352 F. Supp. 2d 940, 948 (D. Neb. 2004), because there Mr. Devor was “given a narrow assignment,” his proffered expert opinion came “in the form of an affidavit (not oral testimony),” and the district court struck his opinions in that affidavit “on relevance, not reliability, grounds.” Opp. at 6. That may all be true, but it is not distinguishable: the fact of the matter is that Mr. Devor’s purported expert opinion was stricken by the district court because, as here, he did “not explain how he reached his ultimate opinions nor [did] he describe the analytical processes he went through” to reach those opinions, and therefore did “not satisfy the second part of the *Daubert* analysis ... [and] [wa]s not particularly helpful to the Court.” *In re Acceptance*, 352 F. Supp. 2d at 948. Plaintiffs next contend that this case differs from *In re Ikon Office Solutions, Inc. Sec. Litig.*, 131 F. Supp. 2d 680, 701 (E.D. Pa. 2001), because Mr. Devor’s opinions there -- which were rejected by that court for failing to “provide sufficient facts in support of [his] conclusions,” *id.* at 700 -- were insufficient to defeat a motion for summary judgment, rather than excluded on the

basis of a formal *Daubert* motion. Fair enough. But that is a distinction without a difference: the whole point is that this would not be the first time (or the second time) that a federal district court has rejected Mr. Devor's supposed expert opinions for the same or similar failings that beset his opinions in this case.

### CONCLUSION

Nothing in Plaintiffs' Opposition can overcome the fact that Mr. Devor purports to offer opinions that are irrelevant and a methodology that is unreliable. For these reasons, in conjunction with all those set forth in the Motion to Exclude, Defendants respectfully request that all of the so-called expert opinions and testimony of Mr. Devor be excluded in their entirety, and not relied upon for any purpose.

DATED: July 7, 2009

/s/ Jennifer G. Levy

Jennifer G. Levy  
Patrick M. Bryan  
John K. Crisham  
**KIRKLAND & ELLIS LLP**  
655 Fifteenth Street, NW  
Washington, D.C. 20005  
(Tel) 202-879-5000  
(Fax) 202-879-5200

Robert J. Muldoon, Jr., BBO# 359480  
Courtney A. Clark, BBO# 651381  
**SHERIN AND LODGEN, LLP**  
101 Federal Street  
Boston, MA 02110  
(Tel) 617-646-2000  
(Fax) 617-646-2222

Attorneys for Defendants  
Teva Pharmaceuticals USA, Inc.,  
Ivax Corporation and  
Ivax Pharmaceuticals, Inc.

*On behalf of all Defendants*

**CERTIFICATE OF SERVICE**

I hereby certify that on July 7, 2009, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Court in MDL 1456.

/s/ John K. Crisham  
John K. Crisham